DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Midwest Division of Survey and Certification
[redacted]

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

CMS Certification Number: [redacted]

September 23, 2016
(Via Overnight Mail)

President/CEO
Indiana Donor Network
[redacted]

Dear Administrator:

On September 20-22, 2016, the Centers for Medicare & Medicaid Services (CMS) conducted a Medicare substantial allegation (complaint) survey of the Indiana Donor Network.

Based on the survey results, CMS has determined that the Indiana Donor Network does not meet the conditions for coverage for organ procurement organizations (OPOs), and is out of compliance with the condition for coverage listed below. Regulations at 42 CFR § 486, Subpart G for Organ Procurement Organizations require that an organ procurement organization must be in compliance with the applicable conditions for coverage.

42 CFR § 486.344 - Evaluation/Management of Potential Donors & Organ Placement and Recovery

We have determined that the deficiencies are so serious they constitute an immediate threat to patient health and safety. In addition, your OPO was found out of compliance with the following condition for coverage:

42 CFR §486.348: Quality Assessment and Performance Improvement (QAPI)

We have determined that the deficiencies are significant and limit your OPO's capacity to render adequate care and ensure the health and safety of your patients. Enclosed is a complete listing of all deficiencies cited.

Enclosed is form CMS-2567, Statement of Deficiencies and Plan of Correction, documenting the Condition- and Standard-level deficiencies found during the recent survey. All deficiencies cited on the CMS-2567 require a Plan of Correction (PoC). You are required to respond **within five calendar days** of receipt of this notice. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction", keying your responses to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date."

An acceptable PoC must contain the following elements:

1. The plan for correcting each specific deficiency cited;
2. Efforts to address improving the processes that led to the deficiency cited;
3. The procedure for implementing the acceptable PoC for each deficiency cited;

4. A completion date for correction of each deficiency cited;
5. A description demonstrating how the OPO has incorporated systemic improvement actions into its Quality Assessment and Performance Improvement (QAPI) program in order to prevent the likelihood of the deficient practice from reoccurring;
6. Procedures for monitoring and tracking to ensure that the PoC is effective and that specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements; and
7. The title of the person responsible for implementing the acceptable PoC.

A PoC for the deficiencies must be submitted by **September 29, 2015**, to:

Centers for Medicare & Medicaid Services
[redacted]

The correction dates on the Plan of Correction must be no later than **October 13, 2016**. There will be a review following receipt of a credible allegation of compliance.

You must sign and date the bottom of the first page of the CMS-2567. You should be aware that copies of the Form CMS-2567 and subsequent plans of correction are releasable to the public upon request in accordance with the provisions at 42 CFR § 401.133.

Deficiencies which resulted in non-compliance with the conditions for coverage must be corrected in order for payment for covered organ procurement services to continue. CMS will terminate your participation in Medicare if you do not achieve compliance with the conditions for coverage by **October 18, 2016.**

If you are satisfied with this decision, you do not need to take further action. If you believe that this determination is not correct, you may request a final Administrative Law Judge (ALJ) review. To do this, you must file your appeal within 60 calendar days after the date of receipt of this decision.

You must file your appeal electronically at the Departmental Appeals Board Electronic Filing System Web site (DAB E-File) at https://dab.efile.hhs.gov. To file a new appeal using DAB E-File, you first need to register a new account by: (1) clicking Register on the DAB E-File home page; (2) entering the information requested on the "Register New Account" form; and (3) clicking Register Account at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB E-File on your behalf.

The e-mail address and password provided during registration must be entered on the login screen at https://dab.efile.hhs.gov/user_sessions/new to access DAB E-File. A registered user's access to DAB E-File is restricted to the appeals for which he is a party or authorized representative. Once registered, you may file your appeal by:

- Clicking the **File New Appeal** link on the Manage Existing Appeals screen, then clicking **Civil Remedies Division** on the File New Appeal screen and,
- Entering and uploading the requested information and documents on the "File New Appeal- Civil Remedies Division" form.

At minimum, the Civil Remedies Division (CRD) requires a party to file a signed request for hearing and the underlying notice letter from CMS that sets forth the action taken and the party's appeal rights. All documents must be submitted in Portable Document Format ("PDF"). Any document, including a request for hearing, will be deemed to have been filed on a given day, if it is uploaded to DAB E-File on or before 11:59 p.m. ET of that day. A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that CMS files. Correspondingly, CMS will also be deemed to have consented to electronic service. More detailed instructions on DAB E-File for CRD cases can be found by clicking the CRD E-File Procedures link on the File New Appeal Screen for CRD appeals.

If you do not have access to a computer or internet service, you may file in writing, but must provide an explanation as to why you cannot file submissions electronically and request a waiver from e-filing in the mailed copy of your request for a hearing. The mailed request should be sent within 60 days of receipt of this notice to the following address:

[redacted]
Departmental Appeals Board
Department of Health and Human Services
[redacted]

Appeal rights can be found at 42 CFR Part 498. The regulation explains the appeal rights following the determination by CMS as to whether such entities meet the requirements for participation in the Medicare program.

If you have any questions regarding this action, please contact [redacted]

Sincerely,

[redacted]
Branch Manager
Non-Long Term Care Certification
& Enforcement Branch

Enclosure – CMS [redacted]

Indiana Department of Health
Indiana Family and Social Services Administration
UNOS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINT K86 09/23/2016
FORM APPROVED
OMB NO. [redacted]

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	[redacted]	A. BUILDING _____ B. WING _____	C 09/22/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
INDIANA DONOR NETWORK	[redacted]

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
Z 000	INITIAL COMMENTS An unannounced substantial allegation survey was conducted by federal surveyors on September 20, 2016 at the Indiana Donor Network in Indianapolis, Indiana, in accordance with the requirements of 42 CFR Part 486, Subpart G for Organ Procurement Organizations. Complaint [redacted] was substantiated, and an Immediate Jeopardy was identified under the Condition for Coverage found at 42 CFR §486.344: Evaluation and Management of Potential Donors and Organ Placement and Recovery. Other findings included noncompliance with the Condition for Coverage found at 42 CFR §486.348: Quality Assessment and Performance Improvement (QAPI). The President/CEO and other staff members were notified of all findings during an exit conference held at the Indiana Donor Network on September 20, 2016 at 4:15 p.m. The President/CEO was notified of the Immediate Jeopardy on September 22, 2016 at 12:50 p.m.	Z 000		
Z 167	486.344 EVAL/MGT OF PTNTL DONORS/ORG PLCMNT & RCVRY The OPO must have written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor. This CONDITION is not met as evidenced by: Based on document review and interview, the OPO failed to ensure compliance with written	Z 167		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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Z 167	Continued From page 1 protocols for donor evaluation that meet current standards of practice. This deficient practice has the potential to effect any future donor's. Findings include: 1) An Immediate Jeopardy was identified as a result of the OPO's failure to verify and document that the potential donor has been pronounced dead in accordance with applicable legal requirements of local, State, and Federal laws, or the equivalent, with supporting documentation, in three of nine donor records reviewed (Donor #1, Donor #2, Donor #3). See Z 171 for details.	Z 167		
Z 171	486.344(b)(1) POTENTIAL DONOR EVALUATION [The OPO must do the following:] Verify that death has been pronounced according to applicable local, State, and Federal laws. This STANDARD is not met as evidenced by: Based on record review and interview, the OPO failed to verify and document that the potential donor has been pronounced dead in accordance with applicable legal requirements of local, State, and Federal laws, or hospital policy, with supporting documentation, for three of nine donor records reviewed (Donor #1, Donor #2, Donor #3). Findings include: During an interview on September 20, 2016 at 9:15 a.m., the Manager, Business Analytics & Regulatory Compliance stated, "There is no state statute for brain death." When an alternative	Z 171		

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Z 171	Continued From page 2	Z 171		

source was requested for the OPO's point of reference for the verification of brain death, the "Guidelines for Determination of Brain Death," Indiana State Medical Association, March 22, 2010, was provided for "Adult Diagnostic Criteria - Patients Above 18 Years of Age," the Manager, Business Analytics & Regulatory Compliance indicated, "This is what we use." When a pediatric point of reference was requested, a copy of the "Proposed Guidelines for the Determination of Brain Death in Infants and Children in the State of Indiana: Being Submitted for Approval by the Indiana State Medical Association" were provided.

On September 20, 2016, review of OPO policy entitled "Verification and Documentation of Brain Death," FS B 3.000, Revision: 9, Effective Date: 12/31/2014, revealed "Purpose: To verify that brain death has been determined and documented using standard clinical practice. 1. The Family Services Coordinator (FSC) will confirm the status of brain death declaration and documentation. 2. The FSC will verify that the following information is included in the brain death note: a. Date and Time of pronouncement b. Physician's signature c. Specific language must be present that states patient has been pronounced dead, impression: brain death or diagnosed brain dead. 3. The FSC should contact the Administrator on Call (AOC) if there is any question concerning the brain death note.

Review of donor records on September 20, 2016 at 11:40 a.m. revealed that Donor #1 was admitted to the hospital on January 5, 2015 with massive subarachnoid hemorrhage. According to the progress notes of the hospital record, "PT

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Z 171	Continued From page 3 (patient) EEG (electroencephalogram) consistent with brain death 1616 TOD (time of death). Reviewed with Dr. A." The brain death note was signed by a nurse practitioner, which is not in compliance with OPO policy "Verification and Documentation of Brain Death," FS B 3.000, Revision: 9, Effective Date: 12/31/2014. The brain death note did not include the results of a neurological exam in accordance with the "Guideline's for Determination of Brain Death," Indiana State Medical Association, March 22, 2010. Review of donor records on September 20, 2016 at 11:40 a.m. for Donor #2 revealed documented results of a cerebral blood flow study with no corresponding neurologic criteria for brain death in accordance with the "Guidelines for Determination of Brain Death," Indiana State Medical Association, March 22, 2010. Review of donor records on September 20, 2016 at 11:40 a.m. for Donor #3 revealed that documentation for a 17-year-old potential donor included only a neurological exam consistent with brain death. Donor #3 had an aborted apnea test due to instability but no further confirmatory testing. According to the "Proposed Guidelines for the Determination of Brain Death in Infants and Children in the State of Indiana: Being Submitted for Approval by the Indiana State Medical Association, Issues to be considered and protocol to be followed relating to brain death examination: 4. Apnea testing: b. If the apnea test cannot be performed as a result of a medical contraindication or cannot be completed because of hemodynamic instability, desaturation to <85%, or an inability to reach a Paco2 of (symbol	Z 171		

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Z 171	Continued From page 4 for greater than or equal to) 60 mm Hg, an ancillary study should be performed." The OPO did not verify that brain death had been determined and documented using standard clinical practice, in accordance with OPO policy. The donor record did not include any other documentation regarding hospital policy under these circumstances. Interview with FSC-1 on September 20, 2016 at 2:20 p.m. revealed that verification of brain death included ensuring a copy of the brain death note is in the donor's chart, also stating that the brain death should include declaration with date and time, signature "depending on hospital policy," and sometimes a form that Dr. X (Medical Director) uses for declaration. FSC-1 stated that "every hospital has a different brain death policy." If an apnea test is aborted, FSC-1 stated that confirmatory testing "goes by hospital policy." The hospital policy was not included in the specified documentation for verification and documentation that brain death has been pronounced in accordance with standard clinical practice, per OPO policy "Verification and Documentation of Brain Death," FS B 3.000, Revision: 9, Effective Date: 12/31/2014. These findings were verified with the Manager, Business Analytics & Regulatory Compliance on 9/20/16 at 3:10 p.m., who stated that there should have been clinical exams for Donor #1 and Donor #2 and Donor #3.	Z 171		
Z 199	486.348 QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT The OPO must develop, implement, and maintain a comprehensive, data-driven QAPI program	Z 199		

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Z 199	Continued From page 5 designed to monitor and evaluate performance of all donation services, including services provided under contract or arrangement. This CONDITION is not met as evidenced by: Based on document review and interview, the OPO failed to implement and maintain a comprehensive Quality assessment and performance improvement (QAPI) program inclusive of performance indicators that are monitored on an ongoing basis and governing body involvement. This deficient practice has the potential to effect any future donor's. Findings include: 1) During interview on September 20, 2016 at 10:20 a.m., the Manager, Business Analytics & Regulatory Compliance stated that there are no benchmarks, indicators, or thresholds as part of the QAPI program but that they are "building it." 2) Upon request for a copy of the QAPI Plan on September 20, 2016 at 10:20 a.m., the Manager, Business Analytics & Regulatory Compliance stated that there is only a draft at this time. 3) During the exit conference on September 20, 2016 at 4:15 p.m., the President/CEO stated that the Governing Board is not notified of reportable events, other than infectious disease transmissions. 4) See Z 200. There is no evidence that a physician's signature or that pronouncement was documented using standard clinical practice in accordance with OPO policy.	Z 199		
Z 200	486.348(a) COMPONENTS OF A QAPI	Z 200		

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Z 200	Continued From page 6 PROGRAM The OPO's QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management, timeliness of on-site response to hospital referrals, consent practices, organ recovery and placement, and organ packaging and transport. The OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained. This STANDARD is not met as evidenced by: Based on document review and interview, the OPO failed to demonstrate objective measures to evaluate performance with regard to OPO activities and actions to ensure that performance improvements are sustained. This deficient practice has the potential to effect any future donor's. Findings include: 1) During an interview on September 20, 2016 at 10:20 a.m. with the Clinical Quality Assurance Coordinator she indciated she is responsible for completeness and accuracy of the donor chart. The Clinical Quality Assurance Coordinator stated that the death note should include a note that the donor is brain dead, signed, dated, and timed or that the family is wanting to withdraw care. The Clinical Quality Assurance Coordinator stated that the death notes are not flagged as a reportable event requiring review and assignment to a manager. The Clinical Quality Assurance	Z 200		

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Z 200	Continued From page 7 Coordinator stated that when corrections are made successfully the chart is closed. There is no evidence of monitoring to ensure that the corrections are sustained. 2) Review of the Organ Donor Records Audit on September 20, 2016 at 10:20 a.m. revealed "Audit Item 4.i. Time and date of pronouncement of death; I. copy of declaration of death note." There is no evidence that a physician's signature or that pronouncement was determined and documented using standard clinical practice, in accordance with OPO policy "Verification and Documentation of Brain Death," FS B 3.000, Revision: 9, Effective Date: 12/31/2014.	Z 200		